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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,291	07/12/2004	Satoshi Yonchara	10873.1449USWO	7884
52835 7590 07/27/2007 HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902 MINNEAPOLIS, MN 55402-0902			EXAMINER ARIANI, KADE	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 07/27/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/501,291	<b>Applicant(s)</b> YONEHARA ET AL.	
	<b>Examiner</b> Kade Ariani	<b>Art Unit</b> 1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 May 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***DETAILED ACTION***

The amendments filed on 05/04/2007, has been received and entered.

Claims 1-30 are pending in this application and were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

All the objections not repeated in the instant Office Action have been withdrawn due to applicant's response to the previous Action.

***Double Patenting Rejection***

The rejection of claims 1-30 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of Yonehara US Patent No. 6,790,665, has been maintained.

Applicant's arguments filed on 05/04/2007 have been fully considered but they are not persuasive.

The applicant argues that claims 1-22 of Yonehara recite a method of determining total hemoglobin, and the claims fail to recite step of pretreating a sample with an FAOD that acts on glycated amino acid other than glycated protein, also Yonehara fails to recite a measuring kit.

The applicant's argument is not found persuasive for the following reasons; claims 1-22 of Yonehara et al. recite the step of treating a sample with FAOD and the reaction between the FAOD and a glycation site of a degradation product of the denatured hemoglobin. One of the ordinary skill in the art would recognize that the glycation site of a degradation product of the denatured protein is a glycated amino acid.

Therefore, It would have been obvious to one of the ordinary skill in the art to use the method of Yonehara et al. in order to measure an amount of a glycated protein in a sample. Furthermore, once an enzymatic determination of a glycated protein was established, providing a measuring kit to determine the amount of the glycated protein would become obvious.

### ***Claim Rejections - 35 USC § 112***

The rejection of claim 6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn due to the applicant's amendment to the claim filed on 05/04/2007.

Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a method of measuring an amount of a glycated protein in a sample where the claim recites "measuring an amount of hydrogen peroxide generated by the redox reaction to determine the amount of glycated protein", but, since the claim does not set forth any steps involved in the measuring an amount of hydrogen peroxide by the redox reaction, it is unclear what method applicant is intending to encompass. A claim is indefinite where it merely recites components of a reaction mixture without any active, positive steps delimiting how this method actually practiced and so it is unclear how the applicant is intending to perform the measurement.

***Claim Rejections - 35 USC § 103***

The rejection of claims 1-30 under 35 U.S.C. 103(a) as being unpatentable over Komori et al. (European patent application, EP1 002874 A2, Published June 24th, 2000) in view Montellano et al. (Biochemistry, 1988, Vol. 27, pp. 5470-5476) and further in view of Ishimaru et al. (Patent number 6,127,138, Date of Patent Oct. 3, 2000), has been maintained.

Applicant's arguments filed on 05/04/2007 have been fully considered but they are not persuasive.

The applicant argues that claim 1 requires the initial step of pretreating a sample with a FAOD that acts on glycated amino acids other than glycated protein.

The applicant's argument is not found persuasive for the following reasons; Komori et al. teaches treating glycated protein and glycated amino acids with fructosyl amino acid oxidase (FAOD) (Page 4, 0030).

Furthermore, at the time the invention was made several FAOD enzymes with varying substrate specificities were known in the art, therefore, it would have been obvious to choose enzymes which would fit for the purpose of a specific analysis.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

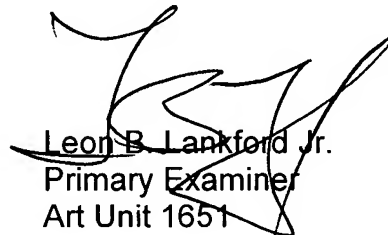
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kade Ariani  
Examiner  
Art Unit 1651

  
Leon B. Lankford Jr.  
Primary Examiner  
Art Unit 1651